



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

T

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,293	08/20/2003	John R. Peery	000952-103	7202
24247	7590	06/14/2007	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EBRAHIM, NABILA G	
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
06/14/2007		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/645,293	PEERY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 2/27/07.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 51-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 51-75 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt of Applicant's remarks and amendments to the claims dated 2/27/07 is acknowledged.

***Status of Claims***

Claims 51-75 pending in the application.

***Status of Office Action:*** Final

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-75 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Laby et al. US 4623330 in view of Portner et al. US 4,360,019 (Hereinafter "Portner"), Magruder et al. US 5238687 (hereinafter "Magruder") and further in view of Mia US 5519002 (hereinafter "Mia") for the reasons set forth in the office action dated 11/22/2006.

***Response to Arguments***

Applicant's arguments filed 8/21/06 have been fully considered but they are not persuasive.

Applicant argues that:

Applicant asserts that Laby et al. does not disclose a back diffusion regulating outlet has a helical flow path selected so that a length of the helical flow path is sufficient to prevent back diffusion of external fluid through the flow path. As clearly described and illustrated, the device of Laby et al. has an outlet that is not back-diffusion regulating and does not have a helical flow path.

To respond: this was not found persuasive because Portner, the secondary reference teaches an infusion system for delivering precisely regulated and variable dosages of drugs. The drug is prevented from flowing back into the reservoir by the valve, which is a spring-loaded in the normally closed position (col. 4, lines 44+).

Applicant argues that Laby et al. teaches away from the present invention as it relies on use of a plunger attached to a helical spring to urge the plunger toward an opening that has no back diffusing mechanism.

To respond: Laby teaches an implantable device (example 4), for delivering a pharmaceutical and veterinary applications (col. 1, lines 5-10). A hollow tubular body adapted to contain a solid, paste or liquid material, one end of said body being open to allow egress of the material, the other end being closed (col. 1, lines 57-63). The hollow body portion comprises a cylindrical tube open at one end, the other end having a base supporting a helical spring to which a plunger is attached which plunger is capable of being urged by the spring toward the opening (col. 1, lines 43-47). The helical spring is made from spring steel wire having a circular cross-section of 0.5 mm in diameter (0.0197 inch), which is within the range set forth in claim 52. Laby also discloses a radially expanding disc to ensure good tight contact between the piston and the walls of the body (col. 2, lines 62-67). Laby also describes the dimensions of his implantable system according to the size of the sheep or cattle as it is used for veterinary use.

Accordingly, Laby does not teach away from an implantable device to deliver an active agent in the living body, however, Laby is deficient in disclosing the back diffusion regulating outlet, which has a helical flow path. The deficiency is remedied by Portner disclosure.

Applicant asserts that Magruder does not teach a back diffusion regulating outlet has a helical flow path selected so that a length of the helical flow path is sufficient to prevent back diffusion of external fluid through the flow path. Magruder and Laby lack a motivation to combine.

To respond: Magruder discloses a delivery implantable device that includes a sleeve to protect the delivery device from transient mechanical forces through a wall that substantially restricts the passage of fluid into the delivery device, i.e. is substantially fluid-impermeable (abstract). The composition of the circumferential sleeve may be of a semipermeable material made of polyamide or polyurethane (col. 9, lines 22, and 23), or in preferably selected from the group consisting of a cellulose ester, a cellulose ether and a cellulose ester-ether, which are cellulosic polymers (col. 9, lines 62-64). Accordingly, it would have been obvious to one of ordinary skill in the art to upgrade the membranes disclosed by Portner and use a semipermeable membranes as it restricts the passage of fluid into the delivery device, i.e. is substantially fluid-impermeable.

Applicant alleges that Mia does not assist in overcoming the recitations of claims 51-54.

To respond: Mia is used as a secondary reference for using LHRH as it was known in art at the time the invention was made.

Applicant asserts that claims 65 and 71 require a water-swellable agent formulation within a reservoir and that the plug has a plurality of circumferential ridges.

To respond: Magruder teaches that compartment 18 which corresponds to the reservoir in the instant application comprises an expandable driving member, which in turn comprises an osmagent (col. 4, lines 62+). It is noted that this osmagent when contacted with water would absorb water and would regulate the flow of the active agent. The reference also teaches that the protective sleeve has two open ends, one for mating with the fully assembled delivery device and the other to allow access of moisture to the semipermeable membrane area. There are also four ridges to stops spaced circumferentially around the inner wall of the sleeve (col. 14, lines 60-64).

Accordingly, the references teach all the limitations of the instant claims and the rejection is deemed proper under USC 35 §103.

#### ***Conclusion***

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

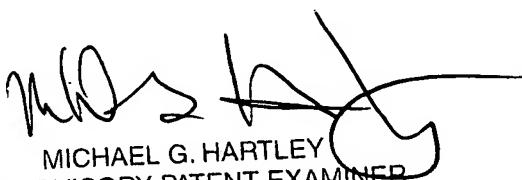
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

6/3/07



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER